

## TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.  
2000-0702.ORI

In Re Application Of: Brian Hawtin

FEB 28 2005

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/701,140	November 21, 2000	TRADEMAKES Lauren Q. Wells	022476	1617	

Invention: FORMULATION

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on December 22, 2004

The fee for filing this Appeal Brief is: \$500.00

- A check in the amount of the fee is enclosed.
- The Director has already been authorized to charge fees in this application to a Deposit Account.
- The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No.
- Payment by credit card. Form PTO-2038 is attached.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**


  
Signature

Dated: February 23, 2005

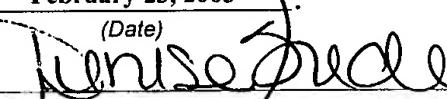
Mark J. Burns, Reg. No. 46,591

Haugen Law Firm PLLP  
 1130 TCF Tower  
 121 South Eighth Street  
 Minneapolis, MN 55402

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

February 23, 2005

(Date)



Signature of Person Mailing Correspondence

Denise L. Siede

Typed or Printed Name of Person Mailing Correspondence

CC:



**CERTIFICATE OF MAILING**

I hereby certify that the foregoing Appeal Brief in application Serial No. 09/701,140, filed November 21, 2000 of Brian Hawtin, entitled "FORMULATION" along with a transmittal cover letter are being deposited with the United States Postal Service as First Class mail, postage prepaid, in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23<sup>rd</sup> day of February, 2005.

Denise L. Siede  
Denise L. Siede  
Assistant to Mark J. Burns  
Attorney for Applicants

Date of Signature: Feb. 23, 2005



PATENT APPLICATION

ATTORNEY DOCKET NO. 2000-0702.ORI

UNITED STATES PATENT AND TRADEMARK OFFICE

---

Date : February 23, 2005  
Re App : Brian Hawtin  
Serial No. : 09/701,140  
Filed : November 21, 2000  
Title : FORMULATION  
Art Unit : 1619  
Examining Attorney : Lauren Q. Wells

---

**APPEAL BRIEF**

Attn: Board of Appeals and Interferences

Appellant's Brief (37 C.F.R. §1.192)

This Appeal Brief is submitted in furtherance of the Notice of Appeal filed on December 22, 2004 and received by the USPTO on December 28, 2004 in the above-identified application.

This Brief contains the following items under the headings and in the order set forth below (37 C.F.R. §1.192(c)):

1. Real Party in Interest
2. Related Appeals and Interferences
3. Status of Claims
4. Status of Amendments
5. Summary of Invention
6. Issues
7. Grouping of Claims
8. Arguments
9. Appendix of Claims

03/01/2005 AWONDAF1 00000048 09701140

01 FC:1402

500.00 DP

**1. Real Party in Interest (37 C.F.R. § 1.192(c)(1)):**

The real party in interest with respect to the above patent application is Thornton & Ross Limited of Yorkshire, United Kingdom.

**2. Related Appeals and Interferences (37 C.F.R. §1.192(c)(2)):**

There are no other appeals or interferences known that are related to the above patent application.

**3. Status of Claims (37 C.F.R. §1.192(c)(3)):**

The claims in the application are 1-33. Of these claims:

Claims 1, 2, 4, 6-8, 10, 14-16, 18-27, and 29-31 are cancelled;

Claims 3, 5, 9, 11-13, 17, 28, 32, and 33 are pending;

Claim 13 is allowed; and

Claims 3, 5, 9, 11, 12, 17, 28, 32, and 33 stand rejected.

The claims on appeal are 3, 5, 9, 11, 12, 17, 28, 32, and 33.

**4. Status of Amendments (37 C.F.R. §1.192(c)(4)):**

Claims 3, 5, 9, 11, 12, 17, 28, 32, and 33 were finally rejected in an Office Action dated July 28, 2004. A non-amending response to the final Office Action was filed on September 28, 2004, and was indicated as being

considered by the Examiner in an Advisory Action dated November 23, 2004.

**5. Summary of the Invention (37 C.F.R. §1.192(c)(5)):**

The present invention concerns a method for treating a skin condition of a human patient through the topical application of an aqueous and oil-phase composition to the patient's skin. This aqueous and oil-phase composition, described at page 5, line 26 - page 6, line 3 of the PCT application publication no. WO 99/60997 ("the application"), specifically includes about 1-5% w/v of an amphoteric surfactant (page 11, lines 16-18), 0.5-4% w/v of an alkoxylated cetyl alcohol (page 12, lines 14-16), and 1-10% w/v of a polar drug selected of either sodium cromoglycate or nedocromil sodium (page 7, lines 8-11).

The treatment of the patient's skin condition is effected by the penetration of the polar drug into the patient's skin. The vehicle which enables the drug penetration into the patient's skin is the combination of an amphoteric surfactant and an alkoxylated cetyl alcohol in the respective recited concentrations in an aqueous and oil-phase composition.

**6. Issues (37 C.F.R. §1.192(c)(6)):**

A. Is the rejection of Claims 3, 5, 11, 17, 28, 32, and 33 under 35 U.S.C. §103(a) as being unpatentable over

Totten et al. (GB 2,202,145) in view of Jacobs et al. (US 5,939,085) and Sang et al. (US 6,143,310) proper?

B. Is the rejection of Claim 9 under 35 U.S.C. §103(a) as being unpatentable over Totten et al. (GB 2,202,145) in view of Jacobs et al. (US 5,939,085), Sang et al. (US 6,143,310), Dener et al. (WO 98/04537) and Haider (1979) proper?

C. Is the rejection of Claim 12 under 35 U.S.C. §103(a) as being unpatentable over Totten et al. (GB 2,202,145) in view of Jacobs et al. (US 5,939,085), Sang et al. (US 6,143,310), and the "Handbook of Cosmetic Science and Technology" proper?

**7. Grouping of Claims (37 C.F.R. §1.192(c)(7)):**

For the purposes of this appeal, since pending Claims 3, 5, 9, 11, 12, 17, 28, and 33 depend from pending independent Claim 32, all rejected claims (3, 5, 9, 11, 12, 17, 28, 32 and 33) stand or fall together.

**8. Argument (37 C.F.R. §1.192(c)(8)):**

A. Appellant's Claims 3, 5, 11, 17, 28, 32, and 33 are unobvious and patentable over Totten et al. '145 in view of Jacobs et al. '085, and Sang et al. '310.

Totten et al. '145 generally disclose dermatological compositions having nedocromil sodium and ethoxylated mixtures of cetyl and stearyl alcohols. The Jacobs et al.

'085 patent is generally directed to film-forming skin smoothing compositions, including emulsifiers such as disodium cocoamphodiacetate. Sang et al. '310 disclose a cosmetic composition, and identify PPG-5 ceteth-20 as a suitable solubilizing agent.

1. The cited references fail to teach or suggest the combination of an amphoteric surfactant and an alkoxylated cetyl alcohol with a polar drug in the claimed concentrations.

The primary essence of the presently claimed invention is the combination of an alkoxylated cetyl alcohol and an amphoteric surfactant in specific concentrations to act as a unique vehicle for penetration of a polar drug into the skin of a patient. The Totten et al. '145 reference describes a topical cream that includes a polar drug such as nedocromil sodium. To stabilize the aqueous and oil-phase composition, Totten et al. '145 describe the use of emulsifying agents in the oil-phase of the composition. Nowhere, however, is the presence of an amphoteric surfactant taught or suggested in the Totten et al. '145 patent. Moreover, nowhere do Totten et al. '145 describe the use of surfactants or emulsifying agents in the aqueous phase of the composition.

The presently claimed amphoteric surfactant is soluble in the aqueous phase of the claimed composition, and is

described at page 11, lines 10-13 of the application as a critical element in assisting skin penetration by the polar drug. It is theorized by the Applicant at page 11 of the application that the utilization of such a water-based amphoteric surfactant may be a primary source of the surprising effectiveness characteristic of the presently claimed composition, which is likely due to substantially greater skin penetration by the polar drug. No disclosure or suggestion is made by Totten et al. '145 of such a water soluble amphoteric surfactant.

The Jacobs et al. '085 patent discloses the use of disodium cocoamphodiacetate as an emulsifying agent for stabilizing oil-in-water emulsions. Although such a material is an amphoteric surfactant, it is not utilized in the Jacobs et al. '085 patent in connection with the polar drug, nor do Jacobs et al. describe the disodium cocoamphodiacetate as an agent for assisting the skin penetration by such a polar drug. The Sang et al. '310 patent is merely cited for its identification of a cetyl alcohol as a solubilizing agent. As such, none of the references teach or suggest the claimed combination.

Moreover, the cited references fail to teach or suggest the claimed concentrations of the alkoxylated cetyl alcohol and the amphoteric surfactant. Namely, Totten et

al. '145 describe oil-phase emulsifying agents in an amount of 10-12% w/w. In particular, Example 1 on page 9 of Totten et al. '145 discloses the following oil phase emulsifying agents as being present in a single composition: 4% w/w glyceryl monostearate, 4% w/w cetostearyl alcohol, 2% w/w Cremophor A6, and 2% w/w Cremophor A25, which together represent a total emulsifier concentration of 12% w/w. Similar concentrations for the oil phase emulsifying agents of Totten et al. '145 are described at Examples 2 and 3 therein. By contrast, the claimed concentration of the alkoxylated cetyl alcohol emulsifying agent is between 0.5 and 4% w/v.

Additionally, the Jacobs et al. '085 patent describes the use of the amphoteric surfactant disodium cocoamphodiacetate in 39% solution at a concentration of 20% w/w. By contrast, the pending claims recite an amphoteric surfactant concentration of between 1 and 5% w/v.

2. The cited references fail to provide an incentive to combine their respective components.

The Examiner has maintained the claim rejections under 35 U.S.C. §103(a) on the basis that it would have been obvious to one of ordinary skill in the art to add the disodium cocoamphodiacetate of Jacobs et al. '085 to the

composition of Totten et al. '145. The Examiner has rationalized this assertion by stating that the motivation behind combining such references lies in the fact that both of such references are directed to oil-in-water emulsions, and that Jacobs et al. '085 describe the disodium cocoamphodiacetate surfactant as providing emulsion stability. It is well established law, however, that "[i]t is insufficient that the prior art disclosed the components of the patented device either separately or used in other combinations, rather there must be some teaching, suggestion, or incentive to make the combination made by the inventor" Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934 (Fed. Cir. 1990), cert. denied, 498 U.S. 920 (1990). Here, no such teaching, suggestion, or incentive is provided in the cited prior art to add the disodium cocoamphodiacetate of Jacobs et al. '085 to the composition of Totten et al. '145. Specifically, the emulsifying agent characteristics described in Jacobs et al. '085 are not wont for lacking in Totten et al. '145, nor would such characteristics lead to the beneficial results of the presently claimed invention. In other words, it would not have been obvious to one of ordinary skill in the art, upon the reading of Totten et al. '145, to search for and add the disodium cocoamphodiacetate of Jacobs et

al. '085 to the composition of Totten et al. '145, as no need or desirability of adding such an additional emulsifying agent is suggested by Totten et al. '145.

As was stated by the court in Elko Standard Corp. v. Tennessee Valley Authority, 808 F.2d 1490 (Fed. Cir. 1986), cert. dismissed, 483 U.S. 1052 (1987) "the question is not simply whether the prior art 'teaches' the particular element of the invention, but whether it would 'suggest the desirability, and thus the obviousness, of making the combination.'" Elko Standard, 808 F.2d at 1498. Contrary to the Examiner's position, there is simply no teaching in the cited prior art suggesting the desirability of combining the disodium cocoamphodiacetate of Jacobs et al. '085 with the compositions described in Totten et al. '145. Moreover, Totten et al. '145 in effect teach away from the presently claimed combination by describing compositions that incorporate emulsifying agents and/or surfactants solely in the oil phase (see page 4, lines 1-16). As such, one of ordinary skill in the art would not be directed under the teachings of Totten et al. '145 to add a water soluble anphoteric surfactant thereto.

3. The claimed compositions exhibit unexpected results over that demonstrated by the cited references.

It is well established law that an initial finding of obviousness may be overcome with a showing that the claimed invention possesses unexpected properties. The seminal case in this aspect of law is In re Papesch, 315 F.2d 381 (CCPA 1963), wherein the court stated that "a compound and all of its properties are inseparable and must be considered in the determination of obviousness" In re Papesch, 315 F.2d at 391. As such, the presence of a property not possessed by the prior art is evidence of non-obviousness.

As stated in the Manual of Patent Examining Procedure §716.02(b), evidence establishing that the differences in results between the claimed invention and that of the prior art should be demonstrated in the specification or in a Declaration. Applicant has, on 3 occasions, submitted Declarations under 37 C.F.R. §1.132 which demonstrate the unexpected results achieved through the use of the claimed composition. In particular, Declarations of Dr. Alan Edwards and supporting experimental results were submitted on September 29, 2003 and on September 28, 2004, each demonstrating the unexpected treatment efficacy of the presently claimed composition as contrasted with the known

and demonstrated treatment failure of the prior art, and specifically that of primary reference Totten et al. '145. In rejecting the presently pending claims, the Examiner has failed to carefully examine the submitted evidence that clearly establishes the unexpected benefits of the present invention.

In order to demonstrate the unexpected nature of the present invention, results obtained through the use of the claimed composition were compared to results obtained through the use of the compositions described in the closest prior art, Totten et al. '145. Such comparisons were described in the Declarations submitted on September 29, 2003 and September 28, 2004, and were supported by experimental results specifically reporting the clinical effectiveness of the respective compositions. The experimental results for the formulation described in Totten et al. '145 were declared by Dr. Alan Edwards as being reported in a publication entitled Nedocromil Sodium Cream in the Treatment of Atopic Dermatitis by H.P. Van Bever and W.J. Stevens in the European Journal of Pediatrics (1989) 149:74. "I am sure that it is the same formulation...because only one formulation of nedocromil sodium was made by Fisons, the assignee of Totten et al. and the supplier of the formulation used in Van Bever &

Stevens" (Declaration of Dr. Alan Edwards submitted on 9/29/03, §6 (comparing formulation results published in Van Bever et al. to the formulation of Totten et al. '145). Dr. Alan Edwards further declared in the submission of 9/28/04 that "the clinical trial reported in Van Bever & Stevens... was, in fact, a trial of the formulation described in the application by Totten et al." (Declaration of Dr. Alan Edwards submitted on 9/28/04, section 6).

The Van Bever et al. publication, in its "Results" section, clearly sets forth the lack of clinical utility of the formulation described by Totten et al. '145. "In conclusion, 4% nedocromil sodium cream, applied during four weeks, twice daily, has no advantage over placebo in the treatment of patients (older children and adults) with atopic dermatitis" (Van Bever et al., last paragraph(emphasis added)). Accordingly, the Van Bever et al publication plainly states that the 4% nedocromil sodium cream (which was declared by Dr. Alan Edwards as being identical to the formulation of Totten et al. '145) is not useful in the treatment of atopic dermatitis. By contrast, the results obtained through the experimental use of the composition of the present invention indicates that such a composition is indeed effective against, for example, atopic dermatitis. Specifically, the experimental results

provided in Exhibit A of the 9/29/03 Declaration of Dr. Alan Edwards, and in the attachment to the 9/28/04 Declaration of Dr. Alan Edwards demonstrate that the claimed composition is clinically effective and provides a high occurrence of beneficial results. "In contrast to the failure of the composition described in Totten et al. '145 and reported by Van Bever et al., the present formulation has been used with benefit by patients" (Declaration of Dr. Alan Edwards submitted on 9/28/04, Section 6). As revealed in Exhibit A of the Dr. Alan Edwards Declaration submitted 9/29/03, 39 of 45 named patients showed improvement in symptoms and signs of atopic dermatitis and/or eczema after using the topical composition of the present invention. Moreover, the attachment to the Dr. Alan Edwards Declaration submitted 9/28/04 provides in its "Summary" section the following passage referring to "Altoderm" as the brand name of the formulation of the present invention:

At the end of the treatment period, a statistically significant difference was seen between the Altoderm and placebo-control group in mean reduction SCORAD total score from baseline. The mean reduction in SCORAD score was -13.2 for Altoderm and -7.6 for placebo (least square means), giving a difference between treatments of -5.6 (95% confidence interval: -10.3, -1.0) in favour of Altoderm ( $p=0.018$ ). A statistically significant difference ( $p<0.05$ ) between treatments in favour of Altoderm was also noted at the second and third of three assessments during the treatment period.

The SCORAD score referred to above is a measure of both signs and symptoms of atopic dermatitis that was developed by a European task force on atopic dermatitis, and was published in Dermatology, volume 186, pages 23-31 (1993). The measure is made up of signs observed by a doctor about the patient and symptoms such as pruritis (itch) and sleep loss reported by the patient. The signs and symptoms are entered into a formula to obtain an overall score. The SCORAD measure is widely accepted as a standard in Europe, and is established as the only measure of disease severity that has been fully tested for validity, repeatability and responsiveness (Arch Dermatol, C. Charman, H.C. Williams, volume 136, pages 763-769 (2000)).

The Declaration attachment of 9/28/04 further states in the "Conclusions" section that "Altoderm represents an effective, safe, and acceptable treatment for atopic dermatitis in children". In view of the findings reported by Van Bever et al. that the formulation of Totten et al. '145 provides no benefit over placebo, the successful treatment of the vast majority of patients receiving topical treatment with the composition of the present invention clearly demonstrates the unexpected beneficial results associated with the claimed composition.

(i) The experimental results from the use of the composition of the present invention are of statistical and practical significance.

The Examiner has maintained that the experimental results provided in attachments to the Declarations of Dr. Alan Edwards submitted on 9/29/03 and 9/28/04 do not have statistical and practical significance. The Applicant, however, strenuously disagrees with the Examiner's position, in that the data generated in the clinical studies and reported in the Declarations of Dr. Alan Edwards submitted on 9/29/03 and 9/28/04 clearly demonstrate widespread beneficial results through the use of the formulation of the present invention, as compared to no effectiveness whatsoever demonstrated by the formulations of the prior art, and particularly that of Totten et al. '145. Exhibit A attached to the Dr. Alan Edwards Declaration submitted on 9/29/03 illustrates that over 87% of the patients being treated with the present formulation showed a reduction in disease severity. Such results demonstrate that the vast majority of patients received beneficial treatment through the use of the presently claimed formulation, while the formulation of Totten et al. '145, as reported in Van Bever et al., provides no benefit over placebo in the reduction of signs and symptoms of atopic dermatitis. Clearly, the results

provided in the Dr. Alan Edwards Declarations are statistically significant. Moreover, as an obvious consequence of having the vast majority of patients demonstrate an overall reduction in disease severity as measured by the SCORAD score and experience a reduction in the painful and irritating symptoms of atopic dermatitis, the results clearly have practical significance as well.

As a further measure of the significance of the unexpected beneficial results associated with the formulation of the present invention over the complete lack of beneficial results provided in the prior art, the "Summary" and "Conclusions" sections of the attachments to the Dr. Alan Edwards Declaration submitted on 9/28/04 present statistical analysis results demonstrating a statistically significant reduction in SCORAD total score, which is a measure of disease severity in atopic dermatitis. As stated therein, "a statistically significant difference was seen between the Altoderm and placebo-control groups in mean reduction in SCORAD total score from baseline" (Dr. Alan Edwards Declaration of 9/28/04, "Summary" section).

The court in In re Hoch, 428 F.2d 1341 (CCPA 1970) stated that unexpected results include "differences in degree of the same property amounting to marked

superiority" In re Hoch, 428 F.2d at 1345 n.5. Here, the discernable reduction in signs and symptoms in atopic dermatitis in a substantial majority of patients receiving treatment with the formulation of the present invention is indeed a marked superiority over applications that result in no such sign and symptom diminishment, as in Totten et al. '145. Accordingly, the submissions made on 9/29/03 and 9/28/04 clearly demonstrate unexpected results of statistical and practical significance.

(ii) The Declarations are commensurate in scope with the pending claims, since the recited components form the acting agents of the formulation tested.

The Examiner has maintained that the experimental results accompanying the Declarations submitted by Dr. Alan Edwards are derived from a formulation not represented by the rejected claims, and particularly by independent Claim 32. The Dr. Alan Edwards Declaration of 9/28/04 specifically attests to the fact that the components recited in independent Claim 32 represent the acting components responsible for the unexpected results demonstrated in the experimental findings. "Indeed, it is the presence of the amphoteric surfactant and the alkoxylated cetyl alcohol in their respected concentrations that provide the beneficial activity in the trial results,

and specifically not the presence of the remaining components making up the Altoderm skin lotion" (Dr. Alan Edwards Declaration of 9/28/04, Section 6).

The Declaration goes on to attest to the fact that the remaining ingredients of the "Altoderm" formulation used in the clinical trials, and which are not specifically recited in independent Claim 32, do not impact the treatment efficacy of the formulation, but rather are present as non-acting components.

The remaining Altoderm components, such as those listed in pending Claim 13, are present in the Altoderm product simply to provide a stable topical substance for application onto a patient's skin. It is evident to those of ordinary skill in the art that a vast array of additive components may be utilized in combination with the acting ingredients of the amphoteric surfactant, alkoxylated cetyl alcohol, and polar drug, while maintaining the efficacy of the claimed composition. In other words, though the Altoderm product utilized in the above-referenced trials contains ingredients in addition to the presently claimed amphoteric surfactant, alkoxylated cetyl alcohol, and polar drug, such additional ingredients are not critical to the efficacy (transdermal transmission) of the polar drug in the topical treatment of skin disorders. Accordingly, the claims as now pending are indeed commensurate in scope with the results obtained in the clinical trials in that only the claimed components, and their associated concentrations, meaningfully contribute to the operation of the Altoderm formulation utilized in the clinical trial.

It follows from the foregoing that the results indicated in the Dr. Alan Edwards Declarations of 9/29/03 and 9/28/04 through the use of the "Altoderm" formulation

is represented by the acting agents recited in pending Claim 32, and are therefore commensurate in scope with the pending claims.

(iii) The experimental results relevant to the treatment of atopic dermatitis and/or eczema in the Declarations submitted by Dr. Alan Edwards provide sufficient evidence for the patentability of independent Claim 32.

The Examiner has maintained that the experimental results contained in the Dr. Alan Edwards Declaration illustrating the effectiveness of the claimed formulation specifically in the reduction of signs and symptoms associated with atopic dermatitis fail to support the pending claims. It is well established that the Applicant need not demonstrate the utility of many examples in order to broadly claim the subject matter. In fact, a Board of Patent Appeals and Interferences opinion cited in the Manual of Patent Examining Procedure §716.02(a) provides an example of this axiom in stating that evidence of unexpected superior therapeutic activity of a claimed compound against anaerobic bacteria is sufficient to rebut *prima facie* obviousness, even without evidence that the compound is effective against all bacteria where the compound is broadly recited in the claim as being an antibiotic (Ex parte A, 17 U.S.P.Q. 2d 1716 Bd. Pat. App. & Inter. (1990)). The unexpected superior therapeutic

activity cited in Ex parte A, therefore, constitutes a sufficient demonstration of unexpected results to itself overcome a *prima facie* rejection of obviousness under 35 U.S.C. §103(a). The facts present in this case appear to be on point with Ex parte A, with the submitted data and Declarant statements clearly demonstrating an unexpectedly superior therapeutic activity of the claimed composition over that shown by the compositions of the prior art, and specifically that of Totten et al. '145.

The Declaration submitted by Dr. Alan Edwards on 9/28/04 specifically points out that, while the experimental results are linked to the effective treatment of atopic dermatitis, those of ordinary skill in the art would readily recognize that the presently claimed composition would also be effective against a vast array of other skin disorders. Section 6 of the 9/28/04 Declaration states as follows:

Although the clinical trials were directed to patients suffering from eczema and/or atopic dermatitis, the claimed composition is also expected to be effective against a variety of other skin disorders such as, for example, the disorders listed in Claim 17 i.e. contact sensitivity, psoriasis, drug sensitivity reactions, aphous ulcers, Behcet's syndrome, pemphigus, urticaria, urticaria pigmentosa, pyoderma gangrenosum, chronic skin ulcers, ulcers associated with Crohn's disease, burns, insect stings/bites, herpetic infections, systemic sclerosis, morphoea, dermal nodular fibrosis and sunburn. It is therefore inappropriate to restrict the pending claims to a

particular skin condition wherein the formulation provides improved transdermal delivery of a polar drug so as to enable significantly wider treatment relevance.

Such a variety of skin disorders against which the formulation of the present invention may be effective are further identified at page 23, lines 11-17 of the application. The usefulness of a polar drug selected from the group consisting of sodium cromoglycate and nedocromil sodium in the treatment of a variety of skin disorders is widely recognized by those of ordinary skill in the art. By way of demonstration that various skin disorders are the target of expected treatment by, for example, nedocromil sodium, the Totten et al. '145 patent, at page 7, lines 10-23, identifies many skin disorders that are expected to be treated by the polar drug.

B. Appellant's Claim 9 is unobvious and patentable over Totten et al. '145 in view of Jacobs et al. '085, Sang et al. '310, Dener et al. '537, and Haider (1979).

Claim 9 of the present application is dependent upon Claim 32, and therefore incorporates all of the limitations embodied therein. The Dener et al. publication is cited for its discussion of cromolyn and nedocromil as being equivalent cromoglycates in the treatment of hyperproliferative and inflammatory skin conditions. The Haider reference is cited for its discussion of the use of

hydrocortisone in combination with sodium cromoglycate in the treatment of severe skin inflammation. Nowhere, however, do either of these references teach or suggest a combination of an alkoxylated cetyl alcohol and an amphoteric surfactant in a polar drug-containing topical composition, nor do such references teach or suggest the unexpected beneficial effects obtained by the present invention. Accordingly, Dener et al. '537 and Haider, whether taken alone or in combination, fail to cure the defects of the cited prior art as described above.

C. Appellant's Claim 12 is unobvious and patentable over Totten et al. '145 in view of Jacobs et al. '085, Sang et al. '310, and "The Handbook of Cosmetic Science and Technology".

Claim 12 of the present application is dependent from Claim 32, and therefore incorporates all of the limitations embodied therein. The Handbook of Cosmetic Science and Technology is cited for its discussion of foams as being interchangeable colloid systems with emulsions. This reference, however, fails to cure the defects of the remainder of the cited prior art, specifically by failing to teach or suggest the combination of an alkoxylated cetyl alcohol and an amphoteric surfactant in a polar drug-containing topical composition. As such, each of the cited references, whether taken alone or in combination, fail to

teach or disclose the formulation as recited in currently pending Claim 32 and all claims dependent therefrom.

D. Conclusion.

For the foregoing reasons, Claims 3, 5, 9, 11, 12, 17, 28, 32, and 33 are unobvious and patentable over the cited prior art references. Applicant therefore submits that all pending claims are allowable on the merits and respectfully requests allowance thereof.

9. Appendix of Claims on Appeal (37 C.F.R. § 1.192(c)(9)):

3. A method according to Claim 32 wherein the amphoteric surfactant is a balanced amphoteric surfactant.

5. A method according to Claim 32 wherein the amphoteric surfactant comprises disodium cocoamphodiacetate.

9. A method according to Claim 32 wherein the composition further comprises a corticosteroid.

11. A method as in to Claim 32 herein the composition is an oil-in-water emulsion.

12. A method according to Claim 32 wherein the composition is a foam.

17. A method as in Claim 32 wherein said skin condition is selected from the group consisting of atopic dermatitis, contact sensitivity, psoriasis, drug

sensitivity reactions, aphthous ulcers, Behcet's syndrome, pemphigus, urticaria, urticaria pigmentosa, pyroderma gangrenosum, chronic skin ulcers, ulcers associated with Crohn's disease, burns, insect stings/bites, herpetic infections, systemic sclerosis, morphoea, dermal nodular fibrosis, and sunburn.

28. A method as in Claim 32 wherein said composition is packaged in a tube, tub, bottle or pressurized aerosol container.

32. A method for treating a skin condition of a human patient, comprising:

(a) providing an aqueous and oil phase composition comprising about 1-5% w/v of an amphoteric surfactant, about 0.5-4% w/v of an alkoxylated cetyl alcohol, and about 1-10% w/v of a polar drug selected from the group consisting of sodium cromoglycate and nedocromil sodium; and

(b) applying said composition to the patient's skin.

33. A method as in claim 32 wherein said alkoxylated cetyl alcohol is selected from the group consisting of polypropoxylated cetyl alcohol and ethoxylated cetyl alcohol.

Respectfully submitted,

HAUGEN LAW FIRM PLLP



Date: February 23, 2005

Mark J. Burns, Reg. #46591  
Attorney for Applicant  
1130 TCF Tower  
121 South Eighth Street  
Minneapolis, MN 55402  
Phone: (612) 339-8300